cytarabine, melphalan) and ASCT. Eligible patients (pts) had relapsed/refractory indolent or transformed NHL or MCL that was relapsed/refractory or in first partial (PR1) or complete remission (CR1). Pts received bortezomib on D-11, -8, -5, and -2 before ASCT. Phase I had 4 dose cohorts (0.8, 1, 1.3, and 1.5 mg/m2) and 3 pts were accrued to each. Any non-hematological ASCT-related toxicity > 2 on the Bearman scale occurring between D-11 and engraftment defined the maximum tolerated dose (MTD). Once the MTD has been reached, another 20 pts were enrolled at this dose to determine a preliminary overall response rate (ORR). Pts who were in CR or PR at D+100 were considered responders.

The study enrolled 42 pts until 8/14/2009. The median age was 58 (34-73) years; with 33 males and 9 females. The commonest diagnoses were MCL (23 pts) and FL (7 pts). The median number of prior therapies was 1 (0-6). The median follow-up was 36 (12-55) months. 13 pts were treated in phase I and 29 pts in phase II. The MTD was initially determined to be 1.5 mg/m2 but it was later decreased to 1 mg/m2 because of excessive GI toxicity and peripheral neuropathy (PN). ORR was 91% at 100 days and 87% at 1 year (y). For all 38 evaluable pts at 1y, responses were CR 84%, PR 3%, and progressive disease 13%. Progression-free survival (PFS) was 83% (95% CI of 68-92%) at 1y, and 60% (41-75%) at 3y. Overall survival (OS) was 93% (95% CI 79-98%) at 1y and 80% (62-90%) at 3y. The commonest NCI grade 3 toxicities were neutropenic fever (20), infection (11), anorexia (9), PN (7), hypotension (6), hypokalemia (5), syncope (5), and 1 pt had a grade 4 prolonged neutropenia. Compared to 23 MCL in CR1 historic controls treated with BEAM and ASCT, ORR was 85% in the BEAM group vs. 96% for the V-BEAM group (p = 0.54). PFS was 85% (64-94%) vs. 85% (65-96%) at 1y and 70% (46-84%) vs.73% (49-87%) at 3y (log- rank p =0.71) for BEAM vs V-BEAM respectively. OS was 88% (68-96%) vs. 96% (73-99%) at 1y and 84% (62-94%) vs. 80% (55-92%) at 3y (log-rank p = 0.74) for BEAM vs. V-BEAM respectively. Toxicities were comparable between groups except for some excess of neutropenic fever and PN in the V-BEAM group.

In conclusion, the addition of bortezomib to standard BEAM (V-BEAM) and ASCT is feasible. Determining relative efficacy of V-BEAM compared to BEAM would require a randomized trial.

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PHASE II TRIAL OF INTRAVENOUSLY ADMINISTERED AMD3100 (PLERIXAFOR) FOR STEM CELL MOBILIZATION IN PATIENTS WITH MULTIPLE MYELOMA UNDERGOING AUTOLOGOUS STEM CELL TRANSPLANTATION FOLLOWING A LENALIDOMIDE BASED INITIAL THERAPY

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Background: Patients with myeloma receiving initial therapy with lenalidomide-based regimens can have difficulty collecting adequate stem cells. Stem cell collection can be enhanced by the CXCR-4 antagonist plerixafor. Plerixafor is typically given subcutaneously (SQ), with collection approximately 11 hours after injection to obtain maximum yield. Intravenous administration can potentially allow more rapid and predictable mobilization compared to the SQ route.
Patients and Methods: Patients receiving initial therapy with a lenalidomide-based regimen and undergoing stem cell collection within 12 months of myeloma diagnosis were enrolled. Patients received GCSF at 10 μg/kg/day for 4 days followed by addition of plerixafor at 0.24 mg/kg/dose starting on day 5. Plerixafor was administered IV early morning (6-7 am) followed by apheresis beginning 4-5 hours later; for a maximum of 5 days. The aims of the study were to determine the proportion of patients reaching a stem cell yield of at least 3 million CD34 cells/kg by second day of apheresis, the safety and tolerability of IV plerixafor, and the overall rate of failure to mobilize (defined as < 2.5 million CD34 cells/kg).
Results: Thirty-seven patients were accrued between December 2009 – April 2011, and 36 were eligible for analysis. The median age was 61 years (range; 28-73); 61% were male. The median time from start of initial therapy to enrollment was 4.6 months (range; 2.6 to 11.1) and the median cycles of lenalidomide were 4 (range; 3-11). Thirty-four (94%) of the patients achieved at least 3 million CD34 cells/kg within 2 days of apheresis. The median CD34 cells/kg after 1 day of collection was 3.9 million (range; 0.7 to 9.2) and after two days of collection was 7.02 million (range: 1.1-16.5). Two patients failed the mobilization (<2.5 million CD34 cells/kg). There were no grade 3 or 4 non-hematological adverse events and one patient experienced grade 4 thrombocytopenia. The most common grade 1 or 2 adverse events seen were gastrointestinal, namely nausea, diarrhea and abdominal pain or bloating. Grade 1 dizziness was reported in 8 patients.
Conclusion: IV plerixafor is an effective strategy for mobilization in this patient group with low rate of failure to mobilize. It is well tolerated with toxicity comparable to the SQ administration. It also offers flexibility in patient scheduling with a convenient schedule for early morning infusion followed by apheresis later in the day.

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THE EFFECTIVENESS AND COST EFFECTIVENESS OF PLERIXAFOR + GCSF VERSUS GCSF ± CHEMOTHERAPY AS SALVAGE MOBILIZATION REGIMENS IN LYMPHOMA AND MULTIPLE MYELOMA PATIENTS

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Introduction: Plerixafor is a novel agent that enhances the mobilization of peripheral blood stem cells (PBSCs) in lymphoma and multiple myeloma (MM) patients whose cells mobilize poorly. Due to the substantial cost associated with its use, we aimed to compare the effectiveness and cost effectiveness of Plerixafor + GCSF (PG) versus GCSF ± Chemotherapy (GC) as salvage mobilization regimens at a stem cell transplant program in Jordan.
Methods: The charts of consecutive heavily pretreated lymphoma and MM patients who had undergone at least one previous attempt of PBSCs mobilization that failed or resulted in an insufficient cell dose for transplant between 2007 and 2010 were retrospectively reviewed. Patients identified received salvage mobilization with GC (prior to 2009) or PG after Plerixafor's FDA-approval. Data collected included demographics, medical histories, apheresis yields and transplant outcome. Costs were calculated based on the Jordanian Ministry of Health list prices and included the costs of medications, apheresis, hospital stay, and adverse effects management. Average cost effectiveness ratio (ACER) was calculated by dividing the average cost of PBSCs mobilization by the reported mobilization success rate.
Results: Seventeen patients were included, five received GC and twelve received PG. A minimum CD34+ cell dose of ≥ 2 x 10^6 cells/kg was collected from 8 patients (67%) in the PG group compared to 3 (60%) in the GC group. All patients successfully mobilized with PG underwent autologous transplant compared to 2 (67%) mobilized with GC. There was no difference in median days to neutrophil or platelet engraftment between the two groups. PG was associated with an average cost of $25,700 and ACER of $38,358/successful mobilization compared to an average cost of $8,570 and ACER of $14,283/successful mobilization for the GC group. (Table1)
Conclusion: Plerixafor as salvage treatment in this group of patients showed an improved success rate of PBSCs mobilization and subsequent transplant but with a significant increase in cost. Prospective comparative effectiveness and cost utility studies are warranted to inform the optimal salvage mobilization regimen. To our knowledge, this is the first study from the Middle East describing the use of Plerixafor and the first with cost effectiveness data outside the US.

Table 1. Patient characteristics, mobilization outcome and cost analysis

Salvage mobilization regimen	GCSF ± Chemotherapy (GC)	Plerixafor + GCSF (PG)
No. of patients	5	12
Average age (SD)	59 (3.7)	46 (12.4)
Median CD34+ collected (106 cells/kg)	2.1	3.9
Patients Collected ≥ 2 x 106 cells/kg CD34+	3 (60%)	8 (67%)
Average mobilization cost	$8,570	$25,700
Average cost effectiveness ratio (ACER)	$14,283/successful mobilization	$38,358/successful mobilization